K021097

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500 Burdick Parkway
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608-764-1919

510(k) Summary

Submitter:

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Date of Summary:

April 4, 2002

Device Name

Proprietary: Spacelabs Burdick Quest Exercise Stress System
Common: Electrocardiograph/Arrhythmia Detector

Device Classification

Classification: Class III
Product Code: 74DSI
Classification: Cardiovascular
Panel

Predicate Device:

Quest Exercise Stress System (K011339)

Description of: the Change

Addition of Cambridge Heart's Alternans Report Classifier software

General Device Description

The Quest Exercise Stress System is a computer based electrocardiograph (ECG) exercise stress test system designed for use with both treadmill and bicycle ergometer exercise protocols. The Quest Exercise stress system provides real time ECG waveforms and calculations to qualified medical personnel while providing automatic or manual control of the exercise equipment.

The Quest Exercise Stress System with T-wave alternans option provides measurement of T-wave alternans measurement in addition to the functions of the ECG. The Alternans Report Classifier software used with the T-wave alternans option provides a preliminary assessment of the alternans report data.

Indication for Use and Intended Population

QUEST is designed to provide ECG information and data to qualified medical personnel for the purpose of assessing the patient's cardiac response to exercise. It is to be used in hospitals, clinics, or physician offices by a qualified and licensed physician, or by trained staff under the direct supervision of that physician.

Stress-test or exercise electrocardiography is used a) when the diagnosis of coronary artery disease is suspected, b) to determine the physical performance characteristics of a patient, c) for post myocardial infarction assessment, or d) for cardiac rehabilitation. The test involves the recording of the electrocardiogram during dynamic or, occasionally, isometric exercise. Disease assessment is most prominent in adult patients. The diagnostic value of exercise testing primarily concerns either ST segment depression present in myocardial ischemia, or elevation seen in infarcts (in comparison to P-Q segment as the isoelectic line). In addition it is important to consider the patient's blood pressure response and physical symptoms.

This instrument is not intended to interpret any exercise test results but is to be used as an aid for the physician to determine normal or abnormal response of the patient to exercise.

QUEST is not intended for long term monitoring of patient ECG signals. Specifically it does not substitute for recommended cardiac monitoring devices recognized by AAMI EC13 especially in the area of alarms.

This instrument (***QUEST***) provides a method of collecting a multichannel ECG for dynamic evaluation of exercise performed by the patient. In order to provoke myocardial ischemia, the degree of stress must be sufficient to exceed the critical level of the patient's myocardial oxygen demand. The

specificity of ST changes in identification of ischemia increases with the degree, time of onset, and when more than one electrocardiograph lead exhibits the abnormality. These patients can walk on a treadmill in which the speed and elevation can be adjusted (automatically or manually) to suit a variety of graded exercise protocols, or pedal an electronically braked bicycle ergometer. If the test subject is unable to walk, isometric exercise can be performed using a handheld dynamometer, or injecting the patient with heart rate stimulants to stress the myocardial system and then use this instrument's monitoring capability. It is operated from a standing position with design consideration given to ergonomic heights, viewing access of the informational display, and control functions. It is cart based, with wheels, to provide easy movement. It can be used in conjunction with echocardiography, nuclear imaging, or pulmonary gas exchange equipment by providing ECG trigger signals and / or treadmill speed and grade levels.

This instrument can also serve as an adult resting interpretive electrocardiograph with the addition of Burdick's resting interpretive program.

The Quest with T-Wave Alternans Option is intended for the measurement of Microvolt T-Wave Alternans* at rest and during ECG stress testing.

The presence of Microvolt T-wave Alternans as measured by the Quest with T-Wave Alternans Option in patients with known, suspected or at risk of ventricular tachyarrhythmia predicts increased risk of a cardiac event (ventricular tachyarrhythmia or sudden death).

The Quest with T-Wave Alternans Option should be used only as an adjunct to clinical history and the results of other non-invasive and/or invasive tests. The interpretive results of the Alternans Report Classifier software should be reviewed by a qualified physician.

The predictive value of T-Wave Alternans for cardiac events has not been established in patients with active, untreated ischemia.

*Microvolt T-wave Alternans is defined as T-wave alternans which (a) is measured from high-resolution multi-segment sensors, (b) is present in leads X, Y, Z, VM or two adjacent precordial leads, (c) is at the level of 1.9 microvolts after signal optimization and subtraction of the background noise level, (d) is at least three standard deviations greater than the background noise level, (e) has an onset heart rate of below 110 beats per minute, and (f) is sustained for all heart rates above the onset heart rate.

Detailed Device Description

The Quest Exercise Stress System simultaneously records and stores a standard 12 lead or 15 lead ECG; a selection of 3, 4, 6, or 12 channels are displayed in real time. ECG recordings may be output to the printer or stored

on disk. The Quest Exercise Stress System controls resting and exercise stages of stress tests conducted according to Bruce, modified Bruce, Naughton, Sub-Maximal, Astrand and other protocols. The Physician may also customize a protocol according to his or her preference.

The Quest Exercise Stress System computes measurements of ST segment slope and level continuously during testing, and displays selected real time 3, 4, 6, or 12 lead (operator selected) ECG traces as well as 12 median beat recordings with optional superimposed median resting beat for reference. All ECG data are provided for evaluation and interpretation by a qualified physician.

The Quest Exercise Stress System w/ Alternans option also computes T-wave alternans (TWA) at rest and during physiological stress. The Alternans Report Classifier software provides a preliminary assessment of the alternans report data. The presence of T-wave alternans is thought to be predicative of increased susceptibility to ventricular arrhythmias.

Device Specifications

PATIENT MODULE: ECG AMPLIFIER and LEADS

Frequency Response: 0.05 to 150 Hz
Notch Filter: 50/60 or OFF, user selectable
Patient Isolation: Meets AAMI ES1, IEC class CF
Defib Protection: Protected to 360 Joules per AAMI EC11
Input Impedance: >20 megohms
Common Mode Rejection: 140 dB (minimum) at 60 Hz
Electrode Offset Tolerance: ± 300 mV
System Noise: < 30 μ Vpp
Pacemaker Pulse Indication: per EC 13
Muscle Artifact Filter: 0.05 to 40 Hz (user-selectable)
Input Channels: Simultaneous acquisition of 8 leads plus 4 derived leads
A/D Conversion: 16 Bits w/oversample
Defibrillator Recovery: 8 sec max.
Standard Cable: 10 electrodes with snap grabbers; cable to instrument is 15 ft. length

CHART RECORDER

Type: Multiple format ECG waveform and alphanumeric printing
Recording Technique: High-resolution thermal dot array, 508 x 200 dots/in.,
Trace Width: 1.0 mm max.
Channel Width: 49.5 mm (3 CH), 33.0 mm (4 CH), 23.0 mm (6 CH)
Lead Group Length (Auto 12-lead): 2.5 or 5.0 seconds
Sensitivity: 5, 10, 20 mm/mV ± 5%, Auto
Frequency response: DC - 150 Hz ± 10% (user selectable)
Calibration Signal: 1.0 mV for 200 msec ± 5%

Speeds: 10, 25, 50 mm/sec ± 2% (crystal controlled)
Paper: Pre-grid thermal, 200 perforated Z-fold pages (8.5 x 11) or European A4, capacity for 300 pages
Feed: Automatic, Queue sensing
Paper Catching: Side-mounted basket

USER ENTRY

Keyboard: 67 full travel keys, QWERTY layout with special dedicated keys
Touchscreen: Integrated into the display monitor, Resistive
Exercise Device Control: Dedicated keys for increase/decrease speed, elevation, or watts, start exercise device, stop exercise device.

DISPLAY MONITOR

Type: High-resolution color raster scan
Size: 15 inch diagonal
Content: 3, 4, 6 or 12 ECG channels, real-time graphs, and alphanumeric data
Sweep Speed: 25 mm/sec ± 5%,
Gain: X2, X1, X0.5 (X1 = 10 mm/mV) ± 10%,
Lead Group: Standard 12-lead
Lead Selection: User selectable
Waveform Display: Eight (8) seconds/lead of ECG (3 Channel Mode)
Display Mount: Adjustable tilt and swivel
Freeze Feature: Split screen format with four (4) seconds of ECG frozen
Memory: Both frozen and continuous ECG display can be recorded from display memory with diagnostic quality
Displayed Data: Stage, Stage Time, Exercise Time, Phase, Protocol, Speed, Grade, RPP, METS / RPE, Blood Pressure, Heart Rate (HR), Target HR, Prompts, Message Line, Selectable Medians, Waveforms

SYSTEM

CPU: Pentium
Memory: 4 MB to 64 MB
Video Memory: 1 MB to 2 MB (Minimum)
Storage: Hard Disk IDE or PCMCIA (40 MB min.), ZIP Drive, Network Drive

REPORTS DURING EXERCISE

12 lead, Rhythm, Average Complex, Screen Capture, Ectopic Beat, Event Identification

FINAL REPORT

Summaries: Exercise Summary Page, Tabular Page (ST, BP, etc.), Trend Graphs (HR, BP, ST), ST Level and Slope (Data summary), Average Complex Summary, Maximum ST, Ectopic Beat Summary, Prelimary assessment of alternans data
Comments: Selectable, User Defined

Setup: User Configurable

ECG COMPUTATIONS

HR Computation: 8 beat average, 30 - 250 BPM, updated every second
ST Parameters: Level, Slope (12 Leads Simultaneously)
ST Reference Points: E-point (QRS Onset), J-Junction (QRS Offset), and ST, user-selectable, variable
QRS Detection Channel: Based on ASVV (Absolute Spatial Vector Velocity)

EXTERNAL INTERFACES

Removable media: PCMCIA Type III Card, PC-compatible, used for data storage and software update
Digital I/O: Three (3) RS232C, PC-compatible serial channels that are user-configurable, (9-pin connector)
Standard Interfaces: NIBP Kinetorr, Oximetry, Bike Ergometer, Ext. Fax/modem, Burdick Database Management System, Debug
Treadmill: T600 Series Treadmills, Dedicated Serial RS232C
Digital Output: TTL Pulse for QRS detection Not for QRS Sync applications).
Analog Scaling: 1.0 V /mV ± 5%, 8 bit res.
Analog Output: Four (4) analog outputs user-selectable between three (3) current ECG leads displayed, Heart Rate, Treadmill Speed/Grade, Ergometer RPM/Workload.
Parallel Printer: 25 pin Centronics

EXERCISE DEVICE CONTROLLER

Displays (digital): Grade displayed in %. Speed displayed in mph, km/h, or rpm. Workload displayed in METS, Calories (Kcal),or Watts
User-Defined Environment: Includes five (5) user-defined configurations and final report, multiple protocols
Protocols: Ten (10)resident protocols: Manual, Bruce, Mod. Bruce, Naughton, Balke, Ellestad, Ramp, Kattus, Astrand, Mod. Astrand.
User-programmable protocols: >20 programmable, >30 stages each with warm-up and recovery
Display Timers: Warm-up, Exercise Test Time, Stage Time, and Recovery Time

ENVIRONMENTAL CONDITIONS

Power: 115/230 VAC ± 10%, 50/60 Hz nominal 200W maximum
Operating Temperature: 50° to 104° F (10° to 40°C)
Humidity: 15 to 85% at 77° to 95°F (25° to 35°C) non-condensing
Barometric Pressure: 425 to 775 mmHg
Storage Temperature: -5° to 130° F (-20° to 55°C)
Storage Humidity: 0 to 95%
System Leakage: <300 μA (<100 μA typ.)

PHYSICAL DESIGN SPECIFICATIONS

Cart Dimensions: 60 x 25 x 30 in. (H x W x D)
Patient Module: 1.4 x4.5 x 3.9 in. (H x W x D), <1 lb.
System Weight: <170 lb. (with options)
Swivel Casters: Four (4), with two (2) locking
Storage: Basket, shelf, or drawer

Device Interfaces

Exercise Equipment:	The Quest Exercise Stress System has been designed and tested for use with the Spacelabs/Burdick T600 Treadmill.
Patient Electrodes:	Patient electrodes designed and approved specifically for use during exercise stress testing should be used at all times with the Quest Exercise Stress System. Measurement of alternating beat to beat T-wave amplitude (alternans) requires the use of the Cambridge Heart Hi-Res™ Electrode or Micro-V™ Electrode in conjunction with other Patient electrodes designed and approved specifically for use during exercise stress testing.

Detailed Device Description

Hardware Overview

Standard Hardware Components

System Cart:	Mounts Computer, display, keyboard, and output devices.
Computer and Keyboard:	IBM compatible, including hard disk and interface cards.
Display:	15-inch color monitor on swivel tilt bracket.
ECG Amplifier	The ECG Amplifier for Alternans measurement is embodied in the PM-3 patient module.. Plugs into computer.
Printer:	Integrated thermal printer
Software:	Integrated System and diagnostic software is provided on hard disk.

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Standard Hardware Accessories

Patient Cable: Set of 10 to 14 detachable lead wires which meet the requirements of 21CFR 898.12 and comply with IEC-601-1; 56.3c part 1.1, General Requirements for Safety.

Individual patient leads are either not detachable, or user detachable with female socket connections such that no conductive surface is exposed when unconnected.

User Manuals: Operators manual supplied standard with every system. Service manual supplied upon request. Physicians Guide to T-Wave Alternans processing supplied with T-wave Alternans Option. T-wave alternans Course Training Manual supplied in conjunction with training course.

Optional Configurations

There are fourteen (14) configurations for QUEST depending on the options purchased.

Configuration 1

The standard configuration which includes a custom cart containing a) the electronics chassis, b) a keyboard, c) treadmill control keys, d) thermal printer, e) a monitor with an integrated tilt, swivel and touchscreen, f) paper tray, g) storage basket, and h) Patient Module. It also includes a T600 Series treadmill connected to the electronics chassis. Both pieces of equipment have an AC input power cord. The lead wires of the Patient Module are fastened to disposable electrodes worn by the patient.

Configuration 2

Optionally the Configuration 1 treadmill can be replaced with a Bike Ergometer.

Configuration 3

Optionally the Burdick Adult Resting Interpretative ECG package can be added to any of the configurations. Its analysis capability is only for resting ECG and cannot be used for exercise data.

Configuration 4

Optionally an external FAX/modem unit can be added to any of the configurations. It is cabled to an RS232C serial cable (COM2) for serial data transmissions to a facsimile machine.

Configuration 5

Optionally an interface to the Burdick ECG data management system can be provided with any of the configurations. An RS232C serial cable (COM3) allows data exchange and storage of reports.

Configuration 6

Optionally a cable for a parallel printer can be added to any of the configurations. Its purpose is to provide another paper output for reports. A cable would be supplied.

Configuration 7

Optionally an external Non-Invasive Blood Pressure (NIBP) unit can be added to any of the configurations. Cables from one of the analog output ports (01, 02, 03, or 04) programmed to ECG or QRS 'pulse' and COM1 for a RS232C connection (if one exists) are used to communicate to that equipment.

Configuration 8

Optionally the ***Quest*** system is providing only an ECG trigger point to synchronize cardiac nuclear imaging equipment. Configuration 1 or Configuration 2 can include cables from QRS 'pulse' or one of the analog output ports (01, 02, 03, or 04) programmed to ECG, to trigger the imaging system. Typically a radio-opaque marker is injected into the patient during peak exercise so that blood perfusion can be evaluated by the imaging system. The ECG trigger point is used to synchronize the resultant image with ventricular contraction. The patients are generally not on a treadmill at that point

Configuration 9

A variation of Configuration 8 is to replace the bike or treadmill with a hand dynamometer (similar interface as a bicycle ergometer). The dynamometer could also be incorporated directly into the nuclear imaging equipment. The cable from ***Quest's*** QRS 'pulse' or one of the analog output ports (01, 02, 03, or 04) programmed to ECG, provides an ECG trigger signal while ***Quest's*** ergometer control (COM1) sets the workload of the dynamometer.

Configuration 10

Optionally the ***Quest*** system is providing only an ECG trigger point to synchronize the echocardiography equipment which evaluates heart wall abnormalities during ventricular contraction. Configuration 1 and Configuration 2 can include cables from QRS 'pulse' or one of the analog output ports (01, 02, 03, or 04) programmed to ECG, to trigger an echocardiography unit.

Configuration 11

Optionally the ***Quest*** system can provide signals for gas exchange analysis equipment used during exercise testing. Configuration 1 or Configuration 2 can be used for cabling of 01 (treadmill speed), 02 (treadmill grade), and 03 (heart rate or ECG). The QRS 'pulse' can optionally be used for heart rate by some equipment manufacturers. These gas exchange systems perform all calculations and require ***Quest*** only to output workload values and heart rate during exercise.

Configuration 12

Quest can be used stand alone to facilitate drug infusion testing which does not require an exercise device. ***Quest*** is used solely to monitor the ECG, perform a "prompting" protocol, and allow the user to enter events. Note: no controls are available for drug delivery, they must be administered by the operator.

Configuration 13

Cardiac Rehabilitation typically utilizes Configurations 1, 2, 4, 5, 6, and/or 7.

Additional flexibility is provided for storage space by optionally offering a drawer or shelf mounted in the cart "frame".

Configuration 14

Quest can be configured with an alternans option, used to measure, provide interpretive results and record Microvolt T-wave alternans using optional software and PM-3 patient interface module. T-wave Alternans measurement to be useful in predicting ventricular tachyarrhythmias and sudden cardiac death. An alternans Operators Manual and Physicians Guide are provided with this configuration.

Software Overview

Capabilities and Functions

The Quest Exercise Stress System w/alternans option software is designed to:

- Input a standard 12 lead and 12 lead + XYZ ECG lead configuration
- Display ECG traces on a CRT monitor
- Record ECG traces on a laser printer
- Detect QRS complexes and compute heart rate
- Compute ECG median beats
- Detect fiducial points on the ECG median beats
- Compute ST and T wave measures (alternans)
- Execute standard exercise protocols with Specified stages and stage times.

Conclusion

Quest with the addition of the Alternans Report Classifier software is substantially equivalent to the currently marketed QUEST system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 8 2002

Spacelabs Medical, Inc.
c/o Mr. Edward M. Basile
King & Spalding
1730 Pennsylvania Avenue
Washington, DC 20006

Re: K021097
Trade Name: Quest Exercise Stress System (QUEST)
Regulation Name: Arrhythmia Detector and Alarm
Regulation Number: 21 CFR 870.1025
Regulatory Class: Class III (three)
Product Code: DSI
Dated: April 4, 2002
Received: April 4, 2002

Dear Mr. Basile:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

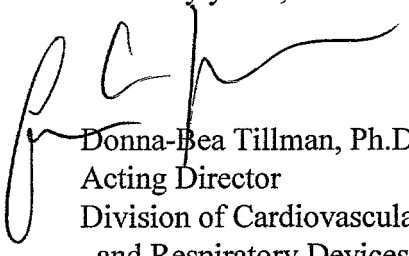
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K021097

Device Name: Quest Exercise Stress System (QUEST)

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular and Respiratory Devices

510(k) Number K021097

(Optional Format 3-10-98)

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